UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,553	09/01/2006	Rajagopal Bakthavatchalam	61387(72021)	4793

21874 7590 08/01/2008

EDWARDS ANGELL PALMER & DODGE LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER	
BERCH, MARK L	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
08/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,553	BAKTHAVATCHALAM ET AL.	
	Examiner	Art Unit	
	/Mark L. Berch/	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33,35-43,45-53,56,57,63-70,73-81,87,88 and 90* is/are pending in the application.

4a) Of the above claim(s) *4,19 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-18,20-31,33,35-43,45-53,56,57,63-70,73-81,87,88 and 90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/06/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The previous election of species requirement is replaced by a restriction requirement (lack of unity):

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 5-18, 20-31, 33, 35-41, 42-43, 45-53, 56-57, 63-70, 73-81, 87-88, 90 drawn to Y=W=N, X=C.

Group II, claim(s) 1-2, 4, 5-17, 19, 20-29, 30, 32-33, 35-41, 42-43, 45-53, 56-57, 63-70, 73-81, 87-88, 90 drawn to X=Y=N, W=C.

Group III, claim(s) 1, 4, 5-16, 19, 20-29, 32-33, 35-40, 42-43, 45-53, 56-57, 63-70, 73-81, 87-88, 90 drawn to X= N, Y=W=C.

Group IV, claim(s) 1, 3, 5-16, 18, 20-29, 31, 33, 35-40, 42-43, 45-53, 56-57, 63-70, 73-81, 87-88, 90 drawn to W=N, Y=X=C

Group V, claim(s) 1-40, 42-43, 45-53, 56-57, 63-70, 73-81, 87-88, 90 drawn to Other.

All claim assignments are in part. That is, no claim falls into just one group.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each group has a different core which constitutes the special technical feature for that group. Thus, Group I is drawn to purines, Group II is drawn to pyrazolopyrimidines, Group II is drawn to pyrazolopyrimidines, Group III is drawn to pyrazolopyridines, Group IV is drawn to

imidazopyridines, and Group V is drawn to groups such as fused triazoles, and fused pyrroles.

The only specific structure feature common to all groups is the NH linker and that is of course not novel.

The election of a purine species is taken to constitute election of Group I with traverse. Thus, all the purines are searched.

The traverse says that there is a lack of burden. This is not true. Group I is classified in 544/276 and 277, but Group II is classified in 544/262, and Groups III and IV are classified in various places in Class 546. Group V is classified in still othe pacles in classes 544 and 546.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-14, 16-18, 20-25, 42-43, 45-46 are rejected under 35 U.S.C. 102(b) as being anticipated by KELLEY, J.L. et al J Med Chem.

Compound 16, Table I, page 1361 corresponds to Y = W = N, all A and B = X = CH, R2=CN, R3 =Cl, and n= 1. Likewise compound 8 with R2=CF3 and compound 19 with R2= methylsulfonyl.

With regard to claims 42-43, these recite a property on which the reference is silent. As is noted below in point 1 of the 35 USC 112, paragraph 1 rejection, this limitation is indefinite. However, even aside from that, it cannot avoid the rejection.

The references show the compound, but are silent on the particular biochemical property. MPEP 2112 states:

"SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY

The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)."

In this case, the "unknown property" is the particular biochemical property. This is unknown because the reference is silent on this property. MPEP 2112 goes on to state:

"A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the

function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection."

Again, the "CHARACTERISTIC" which the prior art is silent on is the biochemical property.

This is not an ordinary inherency situation where it is not explicitly stated what the product actually is. In every reference applied, the reference explicitly teaches exactly what the compound is. In fact, it is the opposite. In a normal inherency situation, the claim is of known structure, and the reference is of unknown structure. Here, the reverse is true, and hence the legal circumstances of inherency-in-the-prior-art do not apply. The only difference is the property about which the reference happens to be silent. Recitation of a property, inherently possessed by the prior art thing, does not distinguish a claim drawn to those things from the prior art, ***In re Swinehart***, 169 USPQ 226, 229.

See for example ***Ex parte Anderson***, 21 USPQ 2d 1241 at 1251, discussion of Rejection E. The claims had "numerical or functional values for certain properties which [the authors of the references] did not measure". The PTO presented no reasoning as to why the prior art material would have been expected to have those properties. Instead, the decision states, "There is ample precedent for shifting the burden to an applicant to reproduce a prior art product whose final structure or properties are, at least, in part determined by the precise process used in its manufacture." (page 1253).

In another example, certain claims of ***Ex parte Raychem Corp.*** 25 USPQ2d 1265 required a linearity ratio of less than 1.2. The decision notes that neither reference discloses any values of the linearity ratio. The PTO presented no reasoning as to what the ratio would be expected to be in the references. The Decision states: "However, this does not end the

inquiry since, where the Patent and Trademark Office is not equipped to perform the needed testing, it is reasonable to shift the burden of proof to Raychem to establish that (1) the argued difference exists...."

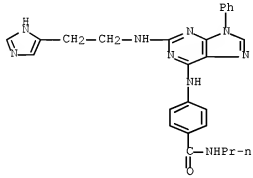
And indeed, there have been a number of cases in which applicants have pointed to silence of the prior art with regard to this or that property: ***In re Pearson***, 181 USPQ 641; ***In re Zierden*** 162 USPQ 102; ***In re Lemin***, 140 USPQ 273; ***Titanium Metals Corporation of America v. Banner***, 227 USPQ 773; ***In re Benner,*** 82 USPQ 49; In re Wilder, 166 USPQ 545; ***Ex parte Kucera***, 165 USPQ 332; ***General Electric Co. v. Jewel Incandescent Lamp Co.***, 67 USPQ 155; ***In re May***, 574 F.2d 1082, 1090, 197 USPQ 601, 607; ***In re Parker***, 43 USPQ 457. Such efforts to avoid anticipation on that basis invariably failed. Going further, if silence about properties of prior art compounds could be relied on, then one could not reject over references with no utility (see ***In re Schoenwald***, 22 USPQ2d 1671), since applicants could always insert the utility into the claim as a property.

It is well settled that the PTO can require an applicant to establish that a prior art product does not necessarily possess the characteristics of the claimed product when the prior art and claimed products are identical or substantially identical. An applicant's burden under these circumstances was described in ***In re Best***, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977) as follows:

> Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, or 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products (footnote omitted).

Claims 1-3, 5-11, 16-18, 20-24, 29-31, 33, 42-43, 45-46 are rejected under 35 U.S.C. 102(a,e) as being anticipated by US 20050124637 A1.

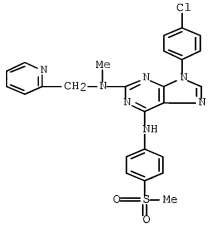
See species 143, which is



This corresponds to Y = W = N, all A, B = X = CH, R2 = CONHPr, R3 = Rx-L-M-Ry, Rx = a bond, L = NRz, Rz = H, M = CH2- CH2, Ry = 4-imidazolyl, and n = p = 0. Page 12 teaches the treatment of cancer and atherosclerosis.

The same table, with that species appears in 60495406, and hence the reference has a date of 8/15/2003, making the rejection under 35 USC 102(e) proper. In addition, the claims are not entitled to benefit of 60549425 because the claims here are broader. For example, R1 or R2 as dialkylaminosulfonyl is not present in 60549425.

In addition, since R3 can be hydroxyalkyl (Rb=OH), species 407 with R5= alkanoyl, R2=Cl anticipates claim 29. Also note compound 589, which has Rz=methyl:

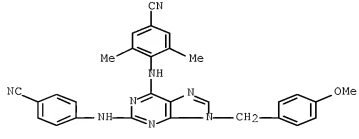


In addition, similar are species 590, 596 (note that Ry can combine with Rz to form ring).

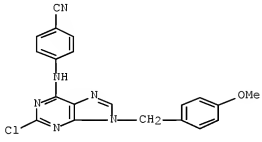
Claims 1-3, 6-11, 16-18, 20-24, 29-31, 36, 38, 41-43, 45-46 are rejected under 35 U.S.C. 102(e) as being anticipated by US 20050124637 A1.

The claims are not entitled to benefit of 60549425 as noted above.

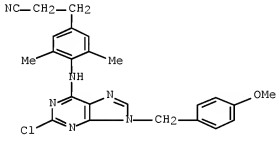
See compound 12 on page 37, which has R2=CN, 2 of the R4 groups as methyl, one R5 as methoxy (thus meeting the requirements of claims 29 and 41), R3 = Rx-L-M-Ry, Rx = a bond, L = NRz, M = bond, Ry = phenyl substituted by CN, and n =1.



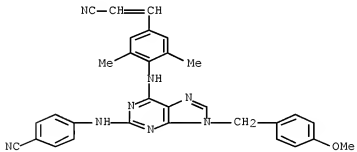
Example A12 has the corresponding R3=Cl species:



The corresponding R2=cyanoethyl compound appears as compound 23 on page 29:

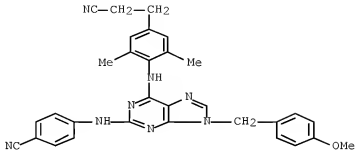


A similar compound appears at the bottom on page 33:

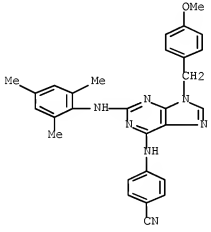


Note that R5 can be cyanoalkenyl, since CN is listed in the third from last line of the Rb definition.

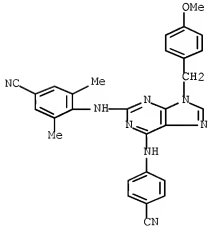
In addition, analogous compound with R2 as cyanoethyl are seen at Page 37, compound 13:



See also compound 71 on page 44:

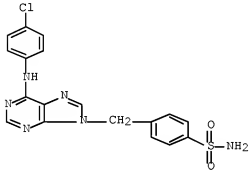


and compound 72:



Claims 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Temple et al.

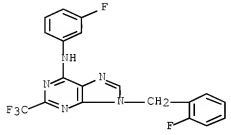
See compound 36, which is:



This corresponds to R5 = aminosulfonyl, R2=halo, n=1. The compounds are antimalarials.

Claims 29-31, 35-38, 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Kelley, et al., European Journal of Medicinal Chemistry Volume 25, Issue 7, September 1990, Pages 623-628.

The reference, table 1, teaches assorted 6-(3-fluoroanilino)-9-(substituted-benzyl)-2-trifluoromethylpurines, where the benzyl substituent is F, nitro, cyano, amino, dimethylamino, CF_3 or methyl. These correspond to R3 = Rx-L-M-Ry, where Rx-L-M- is a bond, and Ry = alkyl substituted by Rb=F, and R2=F. Especially relevant is the meta-F species 16:



As a meta-F, this species also anticipates claim 35.

Claims 64, 66-68, 70, 73-76, 78 rejected under 35 U.S.C. 102(e) as being anticiapted by US 20050288503 A1.

Compounds of Formula II have the CSBP activity (see paragraph 0039), which are the diseases listed in e.g. claim 25. Listed are asthma and COPD (claims 64 and 67), sunburn (claim 66). Many of these have pain as a primary symptom, e.g. all forms of arthritis and hence 68 and 70 and 74-75 are anticipated (note that 74 list pain of disorders such as IBD and rheumatoid arthritis, disorders which appear in claim 25 of the reference). Simialrly, claim 73 lists Neuropathic pain which would fall under the "neurotrauma" of claim 25. Similarly, a primary symptom of eczema, contact dermatitis, and psoriasis, is itch, and hence claim 76 is anticipated. Similarly, cough is a major symptom of asthma, adult respiratory distress syndrome, chronic pulmonary inflammatory disease, chronic obstructive pulmonary disease, and silicosis, all listed in claim 25, and hence claim 78 is anticipated.

The relevant species of Formula II is example 23. Although this does not fall within the claim 1 formula, the rejected claims are not dependent on claim 1, but use the broader formula of e.g. claim 64.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-18, 20-31, 33, 35-41, 42-43, 45-53, 56-57, 63-70, 73-81, 87-88, 90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claims 42-43 are indefinite. There is no single standard "capsaicin receptor calcium mobilization essay" protocol. In fact, no such essay is even mentioned in the specification and the examiner cannot locate this specific essay in the scientific literature. There is a "Capsaicin Receptor Binding Assay" and a "Calcium Mobilization Assay" but these are two completely different things from each other, and neither is a "capsaicin receptor calcium mobilization essay".
2. Rx is listed as C_0-C_3 alkylene, but C0 alkylene is not possible. Alkylene must have at least one carbon.
3. A similar problem occurs in other places, e.g. the C0-C4 alkyl in the R1 definition in claim 47.
4. The M choices must be divalent, e.g. alkylene.

5. The choice of Ry and Rz as alkanone is unclear. An alkanone, e.g. acetone, is a molecule, not a moiety.
6. The same problem occurs for "alkyl ether", which also occurs in Rb and also in R3 of claim 41.
7. The claims provide for R4 groups being combined. That is not possible. R4 choices, taken from the Rb definition are monovalent groups, e.g. halo, nitro, cycloalkyl, etc. They cannot be combined as they have no second valence. Likewise R5.
8. In claim 16, the proviso a few lines below the formula looks like something is barbled. It says "...A2 and A3 are not C1-C6 alkyl if..." But it is R4 which could be alkyl, not A2.
9. A similar problem occurs in claim 29.
10. The function of the term "cellular" in line 2 of claim 47 is unclear. The capsaicin receptor is a cellular receptor, so why is this word here?
11. The scope of claim 64 is unknown. Work on the medical applications of antagonizing the capsaicin receptor is in its early stages, and even less has been done on agonizing the receptor (which is also embraced). Pain has been established as such a condition, but nothing else, and it is not at all clear what else if anything will eventually turn out to fall within this claim language. The specification refers to disorders as varied as COPD, overactive bladder, hiccups, and obesity, but it is not known whether these disorders really do meet the requirements of claim 64, or what else might.
12. Claims such as 65, which depend on two claims are of improper form, as it is unclear whether the compound scope is that of claim 64 or claim 1.

Claims 64-67, 76-81, 88 and 90are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Such a utility cannot be deemed enabled. .

Pursuant to ***In re Wands***, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Some experimentation is not fatal; the issue is whether the amount of experimentation is "undue"; see ***In re Vaeck***, 20 USPQ2d 1438, 1444.

In terms of the treatment of disease, only pain is deemed enabled. Accordingly, claims are not included in this rejection.

The analysis is as follows:

(1) Breadth of claims.

(a) Scope of the compounds. Owing to the immense scope of Ar1, Ar2, R3 and to a lesser degree, R1, trillions of compounds are embraced.

(b) Scope of the diseases covered. As noted in point 11 above, the scope of claim 64 is unknown. Named disorders are asthma, COPD, itch, cough, hiccup, urinary incontinence, and overactive bladder.

(2) The nature of the invention and predictability in the art: The invention is directed toward medicine and is therefore physiological in nature. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors

involved," and physiological activity is generally considered to be an unpredictable factor. See ***In re Fisher***, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(3) Direction or Guidance: That provided is limited. The dosage range information is generic, the same for the many disorders covered by the specification. Thus, there is no specific direction or guidance regarding a regimen or dosage effective specifically for this or that choice.

(4) State of the Prior Art: These compounds are 6, 9-diaryl purines with a particular substitution pattern at the 2-position. So far as the examiner is aware, no diaryl purines of any kind have been used for the treatment of e.g. itch, overactive bladder, etc. .

(5) Working Examples: There is none to the treatment of any disease. There is no biological data of any kind whatsoever. There is in fact, no statement as to which compounds, if any are agonists, which compounds, if any are antagonists, and which is any are inverse agonists and which if any are neutral antagonists, although all four possibilities are mentioned in the specification.

(6) Skill of those in the art: This depends on the particular area of medicine. VR1 antagonists have not been established as effective for treatment of medical conditions aside from treatment of pain, And thus, not for these conditions. Thus, treatment of overactive bladder (OAB) is generally via lifestyle modification and use of certain devices.The drugs used for OAB are antimuscarinic drugs, notably darifenacin, hyoscyamine, oxybutynin,

tolterodine, solifenacin, and trospium. This is a mode of action utterly different from VR1 antagonism. The Apostolidis et al., reference is cited which deals with neurogenic detrusor overactivity (NDO, the treatments for which tend to be the same as OAB) and TRPV1 (VR1, capsaicin receptor). The conclusion says that the datat "suggests that TRPV1 may play a dual role in the pathophysiology of NDO." It is thus clear that research in this area is still at a relatively early stage of just determining the role(s) of TRPV1.

Chronic Obstructive Pulmonary Disease (COPD) is a collection of slowly progressive diseases of the airways, characterized by a gradual loss of lung function. COPD includes chronic obstructive Bronchitis (which involves inflammation and eventual scarring of the bronchi) and emphysema (enlargement and destruction of the alveoli). Emphysema comes in several forms, including Congenital Lobar Emphysema, Bullous Emphysema, Centrilobular Emphysema (Proximal acinar emphysema), Panacinar (panlobular), Distal acinar (paraseptal) as well as Alpha-1 antitrypsin (AAT) deficiency, which is the genetic form of emphysema; patients often have both a form of bronchitis and emphysema. Ordinary chronic bronchitis is sometimes included with COPD even if there is no actual obstruction, and asthmatic bronchitis is generally included in COPD as well. Persons with COPD typically develop smaller air passageways, which can become clogged with mucus and have partially destroyed alveoli. There is no pharmaceutical treatment for COPD per se. Instead, treatment is supportive and designed to relieve symptoms and improve quality of life. Thus, oxygen is often given to partially compensate for the loss of lung function. Bronchodilators can expand passageways in the lungs, Corticosteroids can reduce inflammation and Antibiotics can ward off bacterial infections, but none of these treat the COPD itself. Thus, the skill level in the area of treating COPD itself is especially low.

The pharmaceutical treatment of hiccups has generally involved powerful sedatives (Haldol, Thorazine) or antispasmotics, again a mode of action that is utterly different from that here.

(7) The quantity of experimentation needed: Especially in view of factors 1, 3, 5 and 6, it is expected that the degree of experimentation needed will be high.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. ***In re Wright***, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Mark L. Berch/ whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark L. Berch/
Primary Examiner
Art Unit 1624

8/1/2008